K103050

510(K) SUMMARY: AGFA DX-D 300

Common/Classification Name: Stationary System, 21 CFR 892.1680
Proprietary Name: DX-D 300

OCT 2 9 2010

Agfa HealthCare N.V.
Septestraat 27
B-2640 Mortsel
Belgium
Contact: Phil Cuscuna, Prepared: September 24, 2010
Telephone: (416) 240-7317
Facsimile: (416) 240-7359

A. LEGALLY MARKETED PREDICATE DEVICES

This is a 510(k) for Agfa's DX-D 300, which is a combination of the two predicate devices: Agfa's DX-D Imaging Package (K092669) and Sedecal's X Plus LP Plus x-ray system (K062335).

B. DEVICE DESCRIPTION

The device is a combination of a conventional x-ray system with digital image capture equipment. The new device is a simple combination of the two predicate devices with minor modifications. The DX-D 300 uses Agfa's familiar NX workstation with MUSICA^{2TM} image processing and flat panel detectors of the scintillator-photodetector type (Cesium Iodide or Gadolinium Oxysulfide).

With the new device, users have the ability to control patient exposure settings from the NX workstation. Principles of operation and technological characteristics of the new and predicate devices are the same.

C. INTENDED USE

Agfa's DX-D 300 is indicated for use in providing diagnostic quality images to aid the physician with diagnosis.

Systems can be used with MUSICA2 image processing to create radiographic images of the skeleton (including skull, spinal column and extremities) chest, abdomen and other body parts.

Agfa's DX-D 300 is not indicated for use in mammography.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

Agfa's DX-D 300 has an Indications For Use statement nearly identical to the statements for the two predicate devices (Agfa DX-D Imaging Package and the Sedecal X Plus LP Plus). Intended uses are the same. The devices have the same technological characteristics. Descriptive characteristics and performance data are adequate to ensure equivalence.

Differences in devices do not alter the intended therapeutic/diagnostic effect.

PRODUCT COMPARISON TABLE			
	AGFA DX-D 300 (NEW DEVICE)	**AGFA DX-D Imaging Package (PREDICATE-K092669)**	**Sedecal X-Plus LP Plus (PREDICATE-K062335)**
Communications	Same as predicate	DICOM	N/A
Detector Material	Same as predicate	Gadolinium Oxysulfide (GOS) or Cesium Iodide (CSI) scintillator	N/A
Detector Sizes	Same as predicate	14x17 in. & 17x17 in	N/A
Active Matrix	Same as predicate	3056x3056 (17x17 in.) 3072x2560 (17x14 in.)	N/A
Pixel size	Same as predicate	139 µm	N/A
Fill factor	Same as predicate	100%	N/A
Dynamic Range	Same as predicate	14 bit DR, 12 bit CR	N/A
Maximum Image Acquisitions/hr.	Same as predicate	150	N/A
Image processing	Same as predicate	MUSICA^2	N/A
Operating system	Same as predicate	Windows XP Pro	N/A
Display System	Same as predicate	Standard PC display or separately cleared medical display (e.g. K051901)	N/A
Operator Workstation	Agfa NX with Soft Console Software	Agfa NX	N/A
Power Supply	Same as predicate	47-63 Hz 90-264V auto ranging	U Arm - Single phase, 50/60 Hz 230/240v ±10%
Electrical Safety	Same as predicate	IEC-60601	IEC-60601
Performance Standard	Same as predicate	N/A	21CFR1020.30
Generators	Same as predicate	N/A	Choice of four models, 50-80 KW 400-480v AC, 3 phase, 50/60 Hz
Tubes	Same as predicate	N/A	Choice of three Toshiba models: E7254FX, E7869X and E7884X. Automatic or manual collimation, integrated Dose Area Product (DAP) meter and automatic exposure control.

E. TECHNOLOGICAL CHARACTERISTICS

Agfa's DX-D 300 includes both a traditional U-Arm x-ray system for patient exposure and digital image capture equipment.

The x-ray system includes one of four 50-80 kW generators and one of three Toshiba x-ray tubes. U-arm rotation, height, source-to-image distance and detector rotation are controlled by dual speed motors at the unit or by a remote control. Sensors on the equipment ensure patient safety at all times. An optional rolling patient table is available.

A Cesium Iodide or Gadolinium Oxysulfide flat panel detector is used to capture the image. Previews are available to the operator in as little as one second after exposure. MUSICA^{2}™ image processing provides consistent image quality. DICOM connectivity allows images to be directed to the user's PACS system, archive or hard copy printer. The workstation can also be connected other Agfa computed radiography systems at the facility.

F. TESTING

The new device combines proven technology from both predicates which have been combined to create the new device. The new device includes minor modifications that have been fully tested.

The device has been tested and shown to conform to electronic medical product safety, radiology, and medical imaging standards including:

PRODUCT STANDARDS

- IEC 60601-1-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, plus collateral standard: Electromagnetic compatibility - requirements and tests.
- IEC 60601-1-2: Medical electrical equipment - Part 1-2: General Requirements For Safety - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
- ACR/NEMA PS3.1-3.18: Digital Imaging and Communications in Medicine (DICOM)
- IEC 60601-1-3: Medical electrical equipment – Part 1: General requirements for safety 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment
- IEC 60601-1-4 Programmable Electrical Medical Systems
- IEC 60601-2-7 (1998-02) Medical electrical equipment – Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators
- IEC 60601-2-28 Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis
- IEC 60601-2-32 Particular Requirements For The Safety Of Associated Equipment Of X-Ray Equipment

MANAGEMENT STANDARDS

- ISO 14971 Application of Risk Management to Medical Devices
- ISO 13485 Medical Devices - Quality Management Systems - Requirements For Regulatory purposes

Performance of the complete system has been validated. Sample images have been provided.

No clinical testing was performed in the development of the DX-D 300.

G. CONCLUSIONS

This 510(k) has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Agfa HealthCare N.V.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

OCT 29 2010

Re: K103050
Trade/Device Name: DX-D 300
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: October 14, 2010
Received: October 15, 2010

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

OCT 2 9 2010

510(k) Number (if known): K103050

Device Name: DX-D 300

Indications for Use:

Agfa's DX-D 300 is indicated for use in providing diagnostic quality images to aid the physician with diagnosis.

Systems can be used with MUSICA2 image processing to create radiographic images of the skeleton (including skull, spinal column and extremities) chest, abdomen and other body parts.

Agfa's DX-D 300 is not indicated for use in mammography.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K103050